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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/069,690

08/05/2002

Neil J. Rowley

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EXAMINER

JONES, DAMERON LEVEST

ART UNIT	PAPER NUMBER
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1618

MAIL DATE	DELIVERY MODE
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06/29/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/069,690

Applicant(s)

ROWLEY ET AL.

Examiner

D. L. Jones

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 March 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 3/27/07.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- ☐ Notice of Informal Patent Application
- ☐ Other: _____.

ACKNOWLEDGMENTS

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 3/27/07 has been entered.

Note: Claims 1-9 are pending.

RESPONSE TO APPLICANT'S ARGUMENTS

2. The Applicant's arguments and/or amendment filed 3/27/07 to the rejection of the claims made by the Examiner under 35 USC 103 have been fully considered and deemed non-persuasive for reasons of record in the office action mailed 12/29/06 and those set forth below.

103 Rejection

I. The rejection of claims 1-4, 8, and 9 under 35 USC 103(a) as being unpatentable over Felder (US Patent No. 5,132,409) in view of Schott Glaswerke (DE 29609958) and in further view of Walther (US Patent No. 6,200,658) is MAINTAINED.

II. The rejection of claims 1, 5, 6, 8, and 9 under 35 USC 103(a) as being unpatentable over Albert (US Patent No. 5,545,396) in view of Schott Glaswerke (DE 29609958) and in further view of Walther (US Patent No. 6,200,658) is MAINTAINED.

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III. The rejection of claims 1, 5, and 7-9 under 35 USC 103(a) as being unpatentable over Ardenkjaer-Larsen et al (US Patent No. 6,466,814) in view of Schott Glaswerke (DE 29609958) and in further view of Walther (US Patent No. 6,200,658) is MAINTAINED.

Applicant summarizes each reference and makes the same arguments that have been repeatedly responded to by the Examiner. Applicant asserts that the diagnostic agent of Schott is very different from the diagnostic agent of the instant invention. Thus, the Examiner should not equate the terms. Other assertions made by Applicant include: (1) the Examiner has used piecemeal construction to arrive at the instant invention. (2) Felder does not disclose, teach, or suggest material to be used in the inner surface areas of the vials. (3) Walther does not disclose, teach, or suggest diagnostic agents or even contrast agents per se. (4) The Examiner has used hindsight reasoning to construct the rejection. (5) There are various possible coatings for vials, thus, while the term 'vial' is mentioned in Felder, the document does not elaborate on the feature of improving a vial. (6) There is a lack of motivation to combine the cited references. (7) Albert discloses a silicone coating for its vial. In addition, Applicant states that the term 'silicon' has long been used to refer to silicon only and such shorthand contradicts chemical nomenclature. Hence, without the use of precise or conventional terminology, Applicant's cannot be sure whether the Examiner's words are to be given their literal/conventional chemical meaning or not. As a result, Applicant has concluded that since silica is an essential feature of the claims, the Examiner should establish whether the terms are being used interchangeably or not.

It is once again noted that Applicant is making the same arguments again that the Examiner has already repeatedly responded to. Specifically, Applicant's arguments are not persuasive for reasons already of record in the office actions mailed 12/29/06, 6/16/06, 3/24/06, 12/22/05, and 9/26/05. Also, Applicant is reminded that for a Jepson claim, the preamble acknowledges the prior art teachings. Thus, what is disclosed in Applicant's preamble, a composition comprising a diagnostic agent in a container having a silica inner coating is taught in Schott Glaswerke. Specifically, Schott Glaswerke discloses glass container for storing pharmaceutical or diagnostic solutions. The glass container may be coated with silica to avoid leaching of substances from the glass (page 1, first complete paragraph; pages 1-2, bridging paragraph; page 2, third and fourth complete paragraphs). The words 'the improvement comprising' between the preamble and the body of the claim, discloses what is believed to be unique (the novelty of the invention). Thus, Applicant is claiming that the addition of a non-radioactive metal complex or a hyperpolarized material to the diagnostic composition is novel. Well, it is well known in the art to have a diagnostic agent comprising a hyperpolarized material and a non-radioactive metal complex (see Ardenkjaer-Larsen et al, see entire document, especially, abstract; column 2, lines 44-47; column 3, lines 35-48; column 6, lines 34-48; columns 28-29, claim 1; see also, Albert et al, entire document, especially, abstract; and also, Felder et al, see entire document, especially, abstract; column 2, lines 13-44; column 4, lines 23-40). Furthermore, the teachings of Walther et al disclose coating the interior of a glass with SiO₂. Thus, if it is known to have a diagnostic agent comprising a non-radioactive metal complex and a

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hyperpolarized material and it is also known to have a diagnostic agent in a container that has a silica coating on the inner surface, then the invention would be obvious.

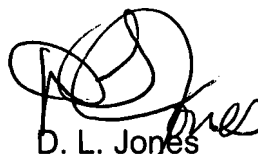
In regards to Applicant's comments about Albert et al, it should be noted that the coating with silicone is only mentioned for the experiment of Example 2. Thus, the teaching of the reference is not limited to silicone. Also, Applicant should note that the Examiner is not equating the term silicone with silica. The reference is being considered for what it teaches as a whole, not for what is disclosed in a single embodiment. Therefore, the reference is not limited to coating with silicone. Furthermore, in response to Applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971). As a result, based on the teachings of the cited prior art the rejections are deemed proper.

3. Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. L. Jones whose telephone number is (571) 272-0617. The examiner can normally be reached on Mon.-Fri., 6:45 a.m. - 3:15 p.m..

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



D. L. Jones
Primary Examiner
Art Unit 1618

June 23, 2007